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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/771,503	01/26/2001	Henry Yue	PC-0027 US	6227

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EXAMINER

CANELLA, KAREN A

ART UNIT PAPER NUMBER

1642

DATE MAILED: 10/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/771,503

Applica

Yue et al

Examiner
Karen Canella

Art Unit
1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on _____.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-21 is/are pending in the application.

4a) Of the above, claim(s) 14-21 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-13 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4

6) Other:

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Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.
2. Claims 2 and 8 have been amended. Claims 1-13 are under consideration.

Claim Rejections Maintained

3. The rejection of claims 1-13 under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial asserted utility or a well-established utility, is maintained for reasons of record..
4. The rejection of claims 1-13 under 35 U.S.C. 112, first paragraph is maintained for reasons of record.
5. Applicant argues that it is clear from Table 1 that the majority of patients having colon disorders such as cancer or polyps showed downregulation of this gene. Applicant further argues that the examiner has provided no sound reasoning to dispute the inventors conclusion that there is a substantial likelihood. That the polynucleotide would be a useful diagnostic indicator for these conditions. This has been considered but not found persuasive. As stated in the previous Office action “an examination of Table 1 finds the experimental data does not support this allegation. The data for the differential expression is put forth as the log base 2 value of the Cy5 to Cy3 ratio. Page 6, lines 19-21 states that Column 3 lists the diseased samples labeled with Cy5 and that column 4 lists the corresponding normal samples labeled with Cy3. If the expression of the gene is lower colon cancer and polyps versus normal tissues the ratio of Cy5 to Cy3 should be less than one in cases of colon cancer or polyps. A value of 1 would be zero in the log base 2 scale, and values of less than one would be negative number in the log base 2 scale. Examination of the log base 2 values shows numbers ranging from -3.64, -3.12, -1.92, +0.14, +0.52, +1.04 for

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polyps and numbers ranging from -3.06, -2.73, -0.53, -2.86, -2.18, -1.99, -0.54, +1.1 and +1.29 for colon tumors. This data indicates that tumor tissue and polyp tissue do not exhibit a decrease in the gene expression of ITL, as they include positive numbers indicating a ratio of Cy5/Cy3 of greater than one. Conversion of the values in Column 1 to base 10 by using the log base 2 value as a power of 2 results in values of 0.081, 0.115, 0.264, 1.10, 1.43, 2.05 for polyps and values of 0.119, 0.151, 0.678, .0.137, 0.220, 0.251, 0.687, 2.14, and 2.44 for tumors, which again does not provide support for the diagnosis of colon disorders comprising cancer or polyps by means of determining the relative expression of polynucleotides encoding SEQ ID NO:1. As these values range from 0.081 to 2.05 for polyp tissue and 0.119 to 2.44 it is not clear how one of skill in the art can make a diagnosis of a colon disorder given the ratios presented in Table 1. The indicated ranges imply that most of the Cy5/Cy3 ratios will be close to "1.0" which results from dividing by the normal value. Given a result of "1.0" one of skill in the art would not be able to make a diagnosis, as this is the value attributed to normal tissue, and it is also a value encompassed by the data for polyps and cancer.

6. All other rejections and objections as stated in Paper No. 9 are withdrawn.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

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will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

October 1, 2002

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
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